

ATTORNEY'S DOCKET NUMBER: 26967U

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| U.S. DEPARTMENT OF COMMERCE, PATENT AND TRADEMARK OFFICE | | DATE: SEPTEMBER <u>21</u> , 2005 |
| TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371 | | U.S. APPLN. NUMBER: (if known): Not Yet Assigned 10/550191 |
| INTERNATIONAL APPLICATION NUMBER: PCT/EP2004/050377 | INTERNATIONAL FILING DATE: 26 March 2004 (26.03.2004) | PRIORITY DATE CLAIMED: 28 March 2003 (28.03.2003) EP |
| TITLE OF INVENTION: SYNERGISTIC COMBINATION COMPRISING ROFLUMILAST AND AN ANTICHOLINERGIC AGENT SELECTED FROM IPRATROPIUM, OXITROPIUM AND TIOTROPIUM SALTS FOR THE TREATMENT OF RESPIRATORY DISEASES | | |
| APPLICANT(S) FOR DO/EO/US: BUNDSCHUH, Daniela; WOLLIN, Stefan-Lutz; WEIMAR, Christian | | |
| <p>Applicant hereby submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:</p> <ol style="list-style-type: none"> <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 USC 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)): <ol style="list-style-type: none"> <input checked="" type="checkbox"/> is transmitted herewith (required only if not transmitted by the International Bureau). <input type="checkbox"/> has been communicated by the International Bureau. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US) <input type="checkbox"/> A English translation of the International Application as filed (35 U.S.C. 371(c)(2)). <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) <ol style="list-style-type: none"> <input type="checkbox"/> are attached hereto (required only if not transmitted by the International Bureau). <input type="checkbox"/> have been communicated by the International Bureau. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. <input checked="" type="checkbox"/> have not been made and will not be made. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). <input type="checkbox"/> A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). <p>ITEMS 10 to 19 BELOW CONCERN OTHER DOCUMENT(S) OR INFORMATION INCLUDED:</p> <ol style="list-style-type: none"> <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. <input checked="" type="checkbox"/> A FIRST preliminary amendment. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment <input type="checkbox"/> A substitute specification. <input type="checkbox"/> A change of power of attorney and/or address letter. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter2 and 35 USC 1821 - 1825 <input type="checkbox"/> A second copy of the published international application under 35 USC 154(d)(4) <input type="checkbox"/> A second copy of the English language translation of the international application under 35 USC 154(d)(4) <input checked="" type="checkbox"/> Other items or information: TRANSMITTAL LETTER; APPLICATION DATA SHEET; INTERNATIONAL PUBLICATION NUMBER: WO 2004/084897 A1, WITH THE INTERNATIONAL SEARCH REPORT (PCT/ISA/210); INTERNATIONAL PUBLICATION DATE: 7 OCTOBER 2004 (07.10.2004), WHICH CONSISTS OF 19 PAGES: 1 PAGE FOR THE COVER SHEET, WHICH CONTAINS THE ABSTRACT, 11 PAGES OF TEXTUAL SPECIFICATION WITH EMBEDDED FORMULAS, 3 PAGES OF 19 CLAIMS, 4 SHEETS OF DRAWINGS; PRELIMINARY AMENDMENT WITH APPENDIXES A AND B TO BE EXAMINED; PCT REQUEST WITH EXECUTED INVENTOR'S DECLARATION (PCT/RO/101); INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY; FIRST NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES (PCT/IB/308); INFORMATION CONCERNING ELECTED OFFICES NOTIFIED OF THEIR ELECTION (PCT/IB/332); NOTIFICATION CONCERNING SUBMISSION OR TRANSMITTAL OF PRIORITY DOCUMENT (PCT/IB/304); POSTCARD FOR EARLY NOTIFICATION OF THE SERIAL NUMBER REQUEST. | | |

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| U.S. APPLICATION NUMBER: (If known): 10/550191 Not Yet Assigned | | INTERNATIONAL APPLICATION NUMBER: PCT/EP2004/050377 | | DATE: SEPTEMBER <u>21</u> , 2005 | |
| The following fees are submitted: | | | | CALCULATIONS | PTO USE ONLY |
| 21. Basic National Fee \$ 300.00 | | | | \$ 300.00 | |
| 22. Examination Fee If International Preliminary Examination Report prepared by USPTO and all claims satisfy Provisions of PCT Article 33(1)-(4) \$ 100.00 All other situations \$ 200.00 | | | | \$ 200.00 | |
| 23. Search Fee (37 CFR 1.445(a)(2) has been paid on the International Application to the USPTO as an International Searching Authority ... \$ 100.00 International Search Report prepared and provided to the Office \$ 400.00 All other situations \$ 500.00 | | | | \$ 400.00 | |
| — Additional fee for specification and drawings filed in paper over 100 sheets (excluding Sequence listing or computer program listing filed in an electronic medium). The fee is \$ 250.00 for each additional 50 sheets of paper or fraction thereof. | | | | | |
| ENTER APPROPRIATE BASIC FEE AMOUNT = | | | | \$ 900.00 | |
| Surcharge of \$130.00 for furnishing the oath or declaration later than _____ 20 _____ 30 months from the earliest claimed priority date (37 CFR 1.492(e)). | | | | \$ 0.00 | |
| CLAIMS | NUMBER: FILED | NUMBER: EXTRA | RATE | | |
| TOTAL | 19-20= | 0 | X \$ 50.00 | \$ 0.00 | |
| INDEPENDENT | 3-3= | 0 | X \$ 200.00 | \$ 0.00 | |
| Multiple dependent claims(s) (if applicable) | | | + \$360.00 | \$ 0.00 | |
| TOTAL OF ABOVE CALCULATIONS = | | | | \$ 900.00 | |
| Reduction by 2 for asserting small entity, if applicable. (Note 37 CFR 1.9, 1.27, 1.28). | | | | \$ 0.00 | |
| SUBTOTAL = | | | | \$ 900.00 | |
| Processing fee of \$130.00 for furnishing the English translation later than _____ 20 _____ 30 months from the earliest claimed priority date (37 CFR 1.492(f)). + | | | | \$ 0.00 | |
| TOTAL NATIONAL FEE = | | | | \$ 900.00 | |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property + | | | | \$ 0.00 | |
| TOTAL FEES ENCLOSED = | | | | \$ 900.00 | |
| | | | | Amount to be: refunded | \$ |
| | | | | charged | \$ |

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U.S. APPLICATION NUMBER:
(If known):
Not Yet AssignedINTERNATIONAL APPLICATION NUMBER:
PCT/EP2004/050377

DATE: SEPTEMBER 21, 2005

10/550191

- a. ☒ One check in the amount of \$ 900.00 to cover the above fees is enclosed.
- b. ☐ Please charge my Deposit Account Number: 14-0112 in the amount of \$ _____ to cover the above fees. (A duplicate copy of this sheet is enclosed.)
- c. ☒ The Commissioner is hereby authorized to charge any additional fees, which may be required, or credit any overpayment to Deposit Account Number: 14-0112.
- d. ☐ Fees are to be charged to a credit card ☐ WARNING: Information on this form may become public ☐ Credit Card Information should not be included on this form.
☐ Provide credit card information and authorization on PTO-2038

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed to request that the application be restored to pending status.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

BUNDSCHUH, et al.

JC05 Rec'd PCT/PTO 21 SEP 2005

Serial Number: Not Yet Assigned

Filed: September 21, 2005

Internatl. Appl. No.: PCT/EP2004/050377

Internatl. Filing Date: 26 March 2004 (26.03.2004)

Title: **SYNERGISTIC COMBINATION COMPRISING ROFLUMILAST AND AN ANTICHOLINERGIC AGENT SELECTED FROM IPRATROPIUM, OXITROPIUM AND TIOTROPIUM SALTS FOR THE TREATMENT OF RESPIRATORY DISEASES**TRANSMITTAL LETTERCommissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith for filing in the U.S. Patent and Trademark Office is the following:

- (1) Application Data Sheet;
- (2) Transmittal Letter to U.S. Designated/Elected Office (DO/EO/US) Concerning Filing under 35 U.S.C. 371;
- (3) International Publication Number: WO 2004/084897 A1, with the International Search Report (PCT/ISA/210); International Publication Date: 7 October 2004 (07.10.2004), which consists of 19 pages:
 - 1 Page for the Cover Sheet, which contains the Abstract,
 - 11 Pages of Textual Specification with embedded formulas,
 - 3 Pages of 19 Claims,
 - 4 Sheets of Drawings;
- (4) Preliminary Amendment with Appendixes A and B to be Examined;
- (5) PCT Request with Executed Inventor's Declaration (PCT/RO/101);
- (6) International Preliminary Report on Patentability;
- (7) First Notice Informing the Applicant of the Communication of the International Application to the Designated Offices (PCT/IB/308);
- (8) Information Concerning Elected Offices Notified of their Election (PCT/IB/332);
- (9) Notification Concerning Submission or Transmittal of Priority Document (PCT/IB/304);
- (10) Check Number: 23671 in the amount of \$ 900.00 for Basic Filing Fee, which includes the Search and Examination Fees, as a Large Entity;
- (11) Postcard for Early Notification of the Serial Number Request.

Respectfully submitted,
NATH & ASSOCIATES PLLCDate: September 21, 2005By: Gary M. Nath
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